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Compound 1080 and 1081
Position Document 1

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I. BACKGROUND

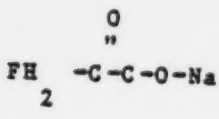
A. Chemical and Physical Properties

Compound 1080, (sodium fluoroacetate) was first used as a rodenticide in the 1940's. It is a hygroscopic, nonvolatile solid that decomposes at about 200°C. Compound 1080 is odorless, essentially tasteless, soluble in water, and slightly soluble in organic solvents.

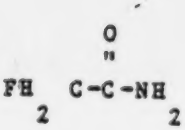
Compound 1081 (fluroacetamide), a hydrolysis product of 1080, was developed in the early 1950's. It is a white crystalline solid that melts at 109°C. It is soluble in water and alcohols but insoluble in organic solvents. Compound 1081 is volatile at room temperature.

Much of the information in this document pertains to Compound 1080. However, because of the chemical and pharmacological similarities of 1080 and 1081, it is reasonable to anticipate that 1081 may cause adverse effects similar to those caused by 1080.

The chemical formulas for 1080 and 1081 are:



(1080)



(1081)

Compound 1080 accumulates to some extent in animals and poses a high secondary hazard to animals that eat poisoned organisms. It is decomposed by soil microorganisms but is relatively persistent (Appendix A).

B. Registered Uses

Although both compounds are systemic insecticides, only rodenticidal uses of 1080 and 1081 are registered in the United States. However, 1081 has been used in other countries to control aphids on sugarbeets, beans, and strawberries.

Currently 3 registrants have 3 Federally registered 1080 products, and 30 registrants have 51 State-registered 1080 products for Federal registration pursuant to 40 CFR 162.17 (California, 46; Nevada, 4; and Colorado, 1). In addition there is one pending application for Federal registration of 1080. There are 2 Federally registered 1081 products which are held by two registrants; no State-registered 1081 products were submitted to EPA under 40 CFR 162.17.

The 1080 products are used in baits to kill chipmunks, ground squirrels, pocket gophers, kangaroo rats, cotton rats, Norway rats, roof rats, house mice, field mice, and other unspecified mammals. Use directions for intrastate products permit both ground and aerial application. Products containing 1081 are used in poisoned baits against Norway and roof rats.

The 1081 labels specify that the product is effective against sewer rats but its use is not specifically restricted to sewers.

C. Production

Information concerning production, sales, and distribution, which is required to be submitted to EPA by Section 7(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is entitled to confidential treatment under the provisions of Sections 7(d) and 10 of FIFRA. Accordingly, such information may not be made available to the public. The production information concerning 1080 and 1081 has been summarized in a separate memorandum for use within EPA (Appendix B).

D. Referral to Office of Special Pesticide Reviews

Compounds 1080 and 1081 were referred to the Office of Special Pesticide Reviews by the Reregistration Task Force because of the chemicals' potential for causing secondary poisoning effects.

II. REGULATORY HISTORY

The principal focus of Federal regulatory history involving Compounds 1080 and 1081 has been on their predacidal uses. While the Agency recognizes that predator control programs, which use meat baits, are not the same as rodent control programs, which use grain and liquid baits, the

regulatory history of the predator uses of Compounds 1080 and 1081 are included as background information.

In response to the public outrage caused by the 1971 alledged misuse of the predacide thallium sulfate that resulted in the deaths of about 20 eagles, the Secretary of the Department of the Interior and the chairman of the Council on Environmental Quality established a committee, chaired by Dr. Stanley Cain, to evaluate the environmental and economic impact of predator control programs and policies. In January 1972, the Cain Report (Appendix A) recommended that

> "...immediate Congressional action be sought to remove all existing toxic chemicals from registration and use for operational predator control. We further recommend that these restrictions extend to those toxicants used in field rodent control whose action is characterized by secondary poisoning of scavengers...(emphasis added).

In June 1971, EPA established a review committee for strychnine, cyanide, and 1080. The committee recommended the cancellation of all uses of thallium sulfate products and the predacidal uses of 1080, strychnine, and sodium cyanide (Appendix C).

In the fall of 1971, several environmental groups, subsequently represented by the Environmental Defense

Fund (EDF), petitioned the EPA Administrator to cancel the registrations of Compound 1080, strychnine, thallium sulfate, and cyanide products for use as rodenticides or destroyers of any vertebrate life because of other effects on nontarget organisms (Appendix D). A notice of the Agency's intent to hold a hearing to determine whether to cancel certain rodenticides was issued in June 1973 (38 FR 16796). The hearing was indefintely postponed the following December because of the lack of evidence required to reach a responsible regulatory decision. EDF renewed its petition for cancellation in March 1976 (Appendix E). The Administrator responded that 1080, 1081, and strychnine would be reviewed in the reregistration and perhaps the rebuttable presumption processes (Appendix F).

In Febuary 1972, the President issued Executive Order 11643 (37 FR 2875), which ordered all agencies to ban the use of chemical toxicants on Federal lands or in any Federal mammal or bird damage control programs where the toxicant was being used to kill a predatory mammal or bird. Although this Order was primarily directed at coyote control programs it prohibited rodent control by chemicals when they have the potential for secondary poisoning. It was modified by Executive Orders 11870 (40 FR 30611) and 11917 (41 FR 22239). Executive Order 11870 allowed heads of executive agencies to authorize emergency use of chemical toxicants and permitted the use of sodium cyanide on Federal lands for

1 year on an experimental basis. Executive Order 11917 allowed the use of sodium cyanide in the M-44 device on Federal lands for mammalian predator control.

In March 1972, the EPA Administrator suspended and cancelled the registrations of predacidal uses of all sodium cyanide, strychnine, and 1080 products (37 FR 5718), thereby prohibiting their sale and distribution in interstate commerce.

The EPA Registration Division is currently reviewing a request for a specific exemption to use 1080 against stray and feral dogs in Guam (41 FR 27121) and the State of Texas has applied for an experimental use permit to use 1080 as a predacide.

III. SUMMARY OF SCIENTIFIC EVIDENCE BY REBUTTABLE PRESUMPTION CRITERIA

A. Acute Toxicity: Hazard to Wildlife

Sections 162.11 (a)(3)(i)(B)(1) and (2) provide that a rebuttable presumption against registration shall arise if the pesticide occurs as a residue immediately following application in or on the feed of a mammalian or avian species representative of species likely to be exposed to such feed in amounts equivalent to the average daily intake of such species at levels equal to or greater than (1) the acute oral LD_{50} for mammalian species or (2) the subacute dietary LC_{50} for avian species.

In order to consider these acute criteria, it is necessary to know which nontarget animals are likely to be exposed and the feeding habits of these organisms, in addition to the LD_{50}'s for the mammals and the subacute dietary LC_{50}'s for the birds.

The Agency is not aware of subacute dietary LC_{50} data on many of the suspected nontarget avian species and acute oral LD_{50} data on many of the suspected nontarget mammalian species for Compound 1080. However, the toxicity values for related nontarget organisms are thought to be similar to those for target species. There are two reasons for this assumption: (1) there is a narrow range of LD_{50} values for 1080 among birds and mammals tested (0.05 mg/kg for nutria to 20.0 mg/kg for turkey vultures; those of most mammals and birds tested ranges from 0.1 to 6.0 mg/kg) (Appendix G) and (2) species of the same genera are biologically similar. Thus, although results of LD_{50} and LC_{50} studies are not available for all nontarget organisms, the acute toxicity data on related species can reasonably reasonably be applied to nontarget organisms that are exposed.

Ingestion of treated bait could occur in two ways: direct feeding on exposed bait or indirect feeding on bait, such as when a predator feeding on a ground squirrel acquires grain contained in the cheek pouches or eats contaminated tissues.

Table 1 shows the appropriate amount of an oat bait containing 0.11% 1080 which is needed to kill selected target and nontarget animals. These species are illustrative of the potential hazard to similar nontarget species throughout the United States when 1080 is used. Values cited were computed using the methodology and graph contained in Appendix H. Thus it can be reasonably anticipated that bait containing 1080 at concentrations equivalent to or above the LD_{50} or LC_{50} will be available to nontarget organisms.

Because of the large number of applications for Federal registration of California-registered 1080 products, State and Federal officials in California were contacted regarding the hazard to nontarget species from 1080 rodent control programs. The officials generally agreed that applicators must exercise caution in rodent control programs when these particular nontarget species reside in or near the treatment area (Appendix I).

B. Effects on Nontarget Organisms

40 CFR Section 162.11 (a)(3)(ii)(C) provides: "A rebuttable presumption shall arise if a pesticide's ingredients...[c]an reasonably be anticipated to result in significant local, regional, or national population reductions in nontarget organisms, or fatality to members of an endangered species."

Table I. Approximate amount of an oat bait containing 0.11% 1080 needed to kill adult individuals of the species shown

Species	Assumed Weight of Animal (kg)	Lethal Dose (mg/kg)[a]	Lethal Amount of Bait/Animal (g)[d]	Daily Feed Consumption (g)	Multiples of Lethal Dose Which May Be Consumed Daily
S[illegible]rmophilus beecheyi (California ground squirrel)	0.500	0.35[b]	0.16	30.00	187
S. nelsoni (San Joaquin Valley antelope squirrel	0.121	0.35[b]	0.03	8.47	223
S. leucurus (Whitetail antelope squirrel)	0.103	0.35[b]	0.03	10.3	312
Dipodomys nitratoides (Fresno kangaroo rat)	0.036	1.00[c]	0.03	5.76	174
D. ingens (Giant kangaroo rat)	0.155	1.00[c]	0.14	14.72	104
D. stephensi (Stephen's kangaroo rat)	0.062	1.00[c]	0.05	8.06	144
Lophortix californicus (California quail)	0.176	4.63[b]	0.74	15.84	21

a) These figures are based on the LD_{100} or LD_{50}.

b) LD_{50} for species or a closely related species

c) LD_{100} for species or a closely related species

d) For oats, 1 g = 35-50 seeds

1. Significant Population Reductions in Nontarget Organisms

The acute oral and subacute feeding data on various organisms for 1080 and 1081 (Appendix J) suggests that a hazard to nontarget animals through direct or indirect ingestion of either 1080 or 1081 might reasonably be anticipated. Notwithstanding the fact that the Agency is aware of no conclusive field data on the effects of 1080 and 1081 on nontarget organisms, the Working Group has decided that the risk criterion for reduction of nontarget organisms has been met and that a rebuttable presumption exists. The Working Group encourages the submission of additional data related to this presumption.

2. Fatalities to Members of an Endangered Species

Compound 1080-treated grains, e.g., wheat, oats, and barley, are used to control ground squirrels in areas inhabited by endangered species of carnivores or scavengers. Frank Schitoskey, Jr., (Appendix K) conducted a study that indicates that 1080 can result in fatalities to members of an endangered species. Specifically, a subspecies of kit fox (Vulpes macrotis arsipus) related to the endangered San Joaquin kit fox (V. marcrotis muticia) was killed when fed a kangaroo rat (Dispodomys sp.) containing 0.74 mg 1080. The related subspecies was used to avoid decreasing the existing numbers of the San Joaquin kit fox. This amount of 1080 would be contained in 0.7 gm (25-30 seeds) of an oat bait containing 0.11% 1080. As indicated in Table 1, a kangaroo rat would be

expected to consume more than 0.7 gm per day. The LD_{50} of the kit fox is 0.22 mg/kg. Therefore 0.74 mg exceeds the LD_{50} of an average size (1.7 kg) kit fox. Consequently, in the event a poisoned animal dies above ground, the San Joaquin fox could be exposed to potentially lethal amounts of 1080.

C. Lack of Emergency Treatment

40 CFR 162.11(a)(3)(iii) provides: "A rebuttable presumption shall arise if a pesticide's ingredient(s)... [h]as no known antidotal, palliative or first aid treatment for amelioration of toxic effects in man resulting from a single exposure."

The Working Group on strychnine and Compounds 1080 and 1081 has considered the following six factors in determining whether this criterion has been met or exceeded: availability of the pesticide, dose likely to be consumed, time factor, efficacy of treatment, availability of emergency treatment, and case histories.

1. Availability of the Pesticides

Federally registered 1080 and 1081 products may be used by licensed pest control operators (LPCO) only. The 1080 products registered in California are to be used only under the supervision of persons authorized by an appropriate State official. There is one 1080 product registered in Colorado which may be used by trained operators only and the 1080 products registered in Nevada may be used only by government agents or with a permit.

Because 1080 products are federally registered for domestic use, accidental child exposure is possible. Directions for federally registered 1081 products state that the product is one of the most effective preparations for direct poisoning of rats in sewers, but does not specifically prohibit domestic use by trained operators. State-registered 1080 products are primarily for nondomestic uses but not all labels limit use to nondomestic areas. The Working Group concurs that formulated 1080 products should not be available to homeowners. This restriction would minimize the possibility that a child will be exposed to the packaged formulation.

2. Dose Likely to Be Consumed

Both 1080 and 1081 are available to pest control operators as concentrates intended for bait preparation. Accidental ingestion of the concentrates could obviously result in exposure to much more that the minimal lethal dose.

Bait preparations which are ready for application range in 1080 concentration from 0.025 to 0.19%. A conservative estimate of the amount of the average accidental exposure to these products would be consumption of one tablespoon (about 15 g) of 0.2% bait. This is equivalent to 30 mg 1080, which is much more than the lethal dose for a 10 kg child based on

the 0.7 mg/kg LD_{50} for humans reported in the U.S. Department of Interior (USDI) review of 1080 (Appendix G).

The recommended concentration of 1081 in baits that are ready for use is 2%. Use directions call for placing 4 oz bait at intervals in the treatment areas. Accidental consumption of one bait placement by a 10 kg child would result in ingestion of more than the minimal lethal dose.

3. Time Factor

Compound 1080 is rapidly absorbed from the gastrointestinal tract. After a lethal dose is absorbed into the bloodstream, the victim will invariably die. Thus immediate treatment is essential. Vomiting must be induced within a few minutes to prevent absorption from the gastrointestinal tract.

Symptoms of 1080 or 1081 poisoning do not appear until a latent period ranging from 30 minutes to over 2 hours has elasped. This lack of symptoms prior to absorption of a lethal dose from the gastrointestinal tract may prevent the victim from getting any treatment prior to the absoption of the fatal dose into the bloodstream.

4. Efficacy of Treatment

Vomiting or gastric lavage will reduce the quantity of 1080 or 1081 absorbed from the gastrointestinal tract if they are done quickly.

Barbiturates may ameliorate the effect of convulsive episodes and have prevented death in a study on fluoroacetate-poisoned dogs when given quickly and when the 1080 dose was four times the LD_{50} or less (Appendix L).

Acetate ion therapy, the ingestion of monoacetin or ethanol and sodium acetate, has prevented death in animal studies (Appendix M). The Agency is not aware of any human poisoning cases where acetate ion therapy was used.

5. Availability of Emergency Treatment

First aid treatment consisting of keeping the patient at rest, inducing vomiting, and administering magnesium sulfate or another cathartic is readily available.

Physicians may readily administer barbiturates, alcohol-acetate ion ingestion, and stomach lavage. Monoacetin is not available in a pharmaceutical grade product. A commercial grade that has not been sterilized is sold, but it is not generally available to hospitals.

6. Case Histories

Human poisoning espisodes from 1080 and 1081 are summarized in Table 2.

USDI reported on accidents from use of 1080 during 1946-49, the first 4 years of its use (Appendix N). Of the 22 cases reported, 4 were suicides and 16 of the 18 accidental cases

Table 2. Human poisoning from Compounds 1080 or 1081

Case	Ingestion	Dose	Causative Agent Verification	Pesticide-Related	Fatal	Status	Mode	Source
			1080					
1.	yes	unknown	yes	yes	yes	adult	suicide	USDI
2.	yes	unknown	yes	yes	yes	adult	suicide	USDI
3.	yes	unknown	yes	yes	yes	adult	suicide	USDI
4.	yes	unknown	yes	yes	yes	adult	suicide	USDI
5.	yes	unknown	yes	yes	yes	child	accident	USDI
6.	yes	unknown	yes	yes	yes	child	accident	USDI
7.	yes	unknown	yes	yes	yes	child	accident	USDI
8.	yes	unknown	yes	yes	yes	child	accident	USDI
9.	yes	unknown	yes	yes	yes	child	accident	USDI
10.	yes	unknown	yes	yes	yes	child	accident	USDI
11.	yes	unknown	yes	yes	yes	child	accident	USDI
12.	yes	unknown	yes	yes	no	child	accident	USDI
13.	yes	unknown	yes	yes	no	child	accident	USDI
14.	yes	unknown	yes	yes	no	child	accident	USDI
15.	yes	unknown	yes	yes	no	child	accident	USDI
16.	yes	unknown	yes	yes	no	child	accident	USDI
17.	Of these 6	unknown	yes	yes	yes	child	accident	USDI
18	cases (17-	unknown	yes	yes	yes	child	accident	USDI
19.	22), 5 invol-	unknown	yes	yes	yes	child	accident	USDI
20.	ved inges-	unknown	yes	yes	yes	child	accident	USDI
21.	tion; in one	unknown	yes	yes	yes	adult	accident	USDI
22.	the mode of exposure was unknown.	unknown	yes	yes	no	adult	accident	USDI
23.	yes	unknown	yes	yes	no	child	accident	literature
24.	yes	unknown	yes	yes	no	child	accident	literature
25.	yes	unknown	yes	yes	yes	adult	suicide	literature
26.	yes	436 mg	yes	yes	yes	adult	accident	Reg. Div. file
27.	unknown	unknown	yes	yes	no	child	accident	PERS[a]
28.	unknown	unknown	yes	probable	no	adult	accident	PERS
			1081					
1.	yes	unknown	yes	yes	yes	child	accident	PERS
2.	yes	unknown	yes	yes	yes	child	accident	PERS
3.	yes	unknown	yes	yes	yes	child	accident	PERS

a) Pesticide Episode Reporting System

involved children. Twelve of the accidental cases resulted from exposure to the souffle cup used in baiting. Four of the accidental cases resulted from drinking 1080 solutions from beverage bottles and one from eating 1080-soaked bread. The route of exposure in the remaining cases is unknown. In these accidental exposure cases, 11 of the children died and 5 recovered; 1 adult died and 1 recovered.

Reports of three cases of human poisoning have been published (Appendix O). Two of these cases were accidents involving children. One case was a suicide. Of the accident cases, one 8-year-old child was found chewing on a 1080 bait placed for rabbit control. The child vomited enroute to the hospital where he received prompt medical attention. After several weeks, the child still exhibited paralysis from the waist down and damage to the nervous system. The amount of 1080 ingested was unknown, and the physician reported that he would have used monoacetin if it had been available.

In the second accident case, an 8-month-old child was found chewing a 1080 bait cup placed behind the refrigerator for rodent control by an LPCO 10 months previously. The family immediately induced emesis by manual gagging. The child was latter flown to a large medical center where she was extensively examined and treated. After release from the hospital, the patient's intellectual and motor performance did not appear to have been diminished.

The low incidence of fatalities among the published cases may be misleading because the medical literature rarely contains accounts of the cases in which treatment was not successful.

EPA Registration Divisions files contain an accident report involving a Colorado man who ingested 436 mg 1080 from a bottle left in a grocery store by an LPCO. Emesis was induced and the man returned home. Five hours later he exhibited generalized convulsions and vomiting. He died enroute to the hospital (Appendix P).

The EPA Pesticide Episode Reporting System (PERS) data includes two nonfatal episodes allegded to have been caused by 1080 (Appendix Q). A child received medical attention after being exposed to the pesticide, which had been used in the home for squirrel control. In the second episode a man alledged that his feelings of tiredness and weakness and his loss of hair were caused by his consumption of a chicken which had eaten flesh from an animal killed by 1080.

Also included in the PERS data is an incident in which three children in Oklahoma were fatally poisoned by ingesting 1080-treated vanilla wafers. The children gained access to a pickup truck owned by a pest control operator who was not licensed in Oklahoma. The treated wafers had been applied in 23 Oklahoma establishments (Appendix R).

7. WORKING GROUP CONCLUSIONS ON THE EMERGENCY TREATMENT CRITERION

Most 1080 and 1081 products are only available to LPCO's or persons authorized by State agricultural personnel. However, for the following reasons the Working Group has determined that a presumption against the registration or continued registration of 1080 and 1081 products exists because of their lack of emergency treatment:

-Once a fatal dose of 1080 or 1081 is absorbed into the bloodstream, the victim will inevitably die;

-Symptoms of 1080 and 1081 poisoning may not occur until after a fatal dose has been absorbed into the bloodstream;

-The current 1080 and 1081 labels do not specifically prohibit use around domestic dwellings where exposure to children is likely; and

-Monoacetin, the potentially most effective medication for 1080 and 1081 poisoning, is not available in a pharmaceutical grade.

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